Sandra Saiz, Chem Sci J 2017, 8:3 (Suppl)
DOI: 10.4172/2150-3494-C1-012

Development and application of rapid microbiology methods in manufacturing and controlling biopharmaceuticals

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Maintaining an aseptic environment during production processes is usually essential for biopharmaceutical manufacturing. Nowadays, microbiological control in the pharmaceutical industry is mainly based upon incubation of microorganisms to detect contamination. Analysis carried out is very time-consuming and results are poorly accurate due to low sensitivity of the equipment. The main goal of this project is to develop and apply rapid microbiology methods to the routine microbiological control of a pharmaceutical processing plant, under GMP conditions. For this, there are two different objectives to deal with: microbial detection and identification. Firstly, regarding rapid detection, a real-time air-borne microbial detection system has been validated to apply it to an aseptic production chain. This system is based on laser-induced fluorescence, which permits to distinguish between viable and non-viable particles present in the air, as the laser excites estearases in living microorganisms. The advantage of this system in front of the traditional air-sampler is that viable but non culturable microorganisms are also detected, in addition, it is real-time measuring, which makes problem-solving faster. Secondly, a rapid identification system based on MALDI-TOF has been validated, which permits to perform identifications from different contamination sources in less than 24 hours. In addition, a sequencing-based identification method has been developed for specific cases when molecular identification is required by authorities or MALDI-TOF can't provide an accurate identification. Also, a comparison between both methods has been performed regarding internally detected microorganisms. In conclusion, the setting up of these techniques will improve the sensitivity and quality of microbiological control and will also be time and cost saving for the company. In conclusion, the setting up of rapid microbiological methods will improve the sensitivity and quality of microbiological control in biopharmaceutical production processes, therefore improving product safety.

Biography

Sandra Saiz Balbastre has a degree in Biotechnology from Universitat Politecnica de Valencia and MSc in Pharmaceutical and Biotechnological Industry-Universitat Pompeu Fabra in Barcelona. Currently, she is finishing her Industrial PhD in the pharmaceutical company Reig Jofre Laboratories in Barcelona in collaboration with Universitat Autonoma de Barcelona.

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